REMARKS/ARGUMENTS

Claims 1-19 have been cancelled, claims 20-77 have been added.

Appropriate fees have been paid with submission of this paper as calculated on the Fee Transmittal Sheet.

The claims have been reformulated to better describe the present invention and clearly distinguish it from the cited references. Basis for the amendments is as follows:

In new Claim 20, the fact that this is a system for alleviating phantom limb pain finds basis in the original claim 1 as filed and selectively delivering stimulation signals to a patient finds basis in the first sentence of the specification and on page 14, lines 22 where it reads "it has been determined by the present inventor that a plurality of signals may be generated by a signal generator 12 and sent to the electrodes 14, thereby stimulating various portions of nerve 20" (It is submitted that the nerve is implicitly that of a patient). The prosthetic limb comprising a plurality of sensors can find basis in claims 7 and 8 as filed. The signal generator finds basis claim 1 as filed and that it produces stimulation signals that trigger the stimulation of one or more selected sensory nerve fibres, finds basis on page 14, lines 20-22 which states "...a plurality of signals may be generated by signal generator 12 and sent to electrodes 14, thereby stimulating various portions of nerve 20." The electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated finds basis in claim 10 as previously filed.

The basis for the microprocessor which receives the sensory signals and controls the signal generator as described finds basis on page 17, lines 4-7 which states "...accomplished by providing a microprocessor in conjunction with signal generator 12 which is programmed to accept signals produced by sensors 50, transducing them to be electrical signals sent to nerve 30

by signal generator 12." That the sensations provided to the patient appear to arrive from the prosthetic limb, finds basis on page 17, lines 17-24. That the selection of one or more sensor nerve fibres is based on feedback from the patient regarding which sensory nerve fibres correspond to which of the one or more sensors, finds basis on page 17, line 26 to page 18, line 3. Means for transmitting the sensory signals from the sensor to the processor finds implicit basis on page 17, lines 5-6, where it is clear that the signal generator is programmed to accept signals produced by the sensors and consequently such means must exist. Furthermore, examples of such means can be found on the same page lines 7-11. Finally, basis for the means of transmitting the stimulation signals to the selected sensory nerve fibres finds implicit basis in that the "electrical signals are sent to the nerve 30" on page 17, line 7 and also an example of such means are described in the form of a nerve cuff described on pages 13 and 14.

Basis for the plurality of electrodes adapted for implantation in close proximity to the severed limb nerve and wherein each electrode is in close proximity to different sensory nerve fibers of the severed limb nerve can be found in the original claim 1, lines 5-8, in combination with original claim 3, lines 18-20.

Claim 21 finds basis on page 15, lines 10-11 which states "...the choice of stimulation patterns may be controlled by the amputee." and on page 16, lines 7-9 which states "many other patterns that are determined in part by the reported sensations elicited in the amputee and by the expressed preference of the amputee."

Claim 22 finds basis on page 18, lines 13-18 which states "When not in use, stimulation may still be applied by signal generator 12 to provide cortical stimulation to keep pain sensation from being interpreted by amputee."

Regarding Claims 23, 24, 25 and 26, basis that the signal generator can be located outside the body or inside the limb stump can be found on page 11, lines 20 and 23. That it can be located inside the body finds implicit basis in that it can be located inside the limb stump. Basis that the signal generator can be located in the prosthetic limb can be found on page 16, lines 13-15. That the microprocessor can also be located with the signal generator in these four locations find implicit basis in the description on page 17, lines 4-7 which reads "In a preferred embodiment, this may be accomplished by providing a microprocessor in conjunction with signal generator 12 which is programmed to accept signals produced by sensor 50, transducing them to be electrical signals sent to nerve 30 by signal generator 12". Thus the microprocessor is implicitly present wherever the microprocessor is shown. Consequently basis is provided for claims 23, 24, 25 and 26.

Claim 27 finds basis on page 8, lines 1-3 which states "provide sensory feedback parameters of a prosthetic limb, such as touch, pressure, force, slip, joint position or temperature information;".

Claim 28 finds basis in original Claim 6.

Claim 29 finds basis in Fig. 1 (22A and 22B) and page 12, lines 2-5 which states "...signals from signal generator 12 may pass through external cable 18 to transmitting antenna 22A, across the skin of the amputee to receiver antenna 22B, and then through cable 16 to electrodes 14."

Claim 30 finds basis on page 18, line 16-18 in combination with the last identified passage.

Claim 31 finds basis on page 11, lines 20-21 which states "Signal generator 12 may be implanted in limb stump 10 and connected directly to electrodes 14 by suitable biocompatible cabling…"

Claims 32, 33, 34 and 35 find basis on page 15, lines 15-20 which states "In one method, the voltage, current and charge density per stimulation impulse is preferably in the range of 10-1000μs un duration, preferably negative going if monophasic, preferably negative/positive if biphasic, and with current amplitude preferably in the range of 1-10 times the threshold current value for first recruitment of large-diameter sensory fibers…"

Claim 36 and 37 find on page 15, lines 11-12 which states "The amputee may adjust the amplitude and frequency of signals…"

Claim 38 finds basis in original Claims 2 and 3.

Claim 39 finds basis on page 14, lines 1-3 which states "…electrodes 14 are placed within individual chambers 23 within nerve cuff 30. Chambers 23 are formed by ridges 24 extending into the lumen of nerve cuff 30.

Claim 40 finds basis on page 8, lines 17-24 which states "In a further embodimentm nerve cuff is multi-chambered, and each of the electrodes is segregated into one chamber of the nerve cuff, each electrode thereby being placed in close proximity to a different portion of the nerve. Alternatively, one or more catheters can provide selective delivery of pharmacological agents to the nerve stumps for the treatment of pain." and in Fig. 2 (see catheters 25).

Claim 41 finds basis on page 20, lines 4-6 which states "For example, it may be appropriate to have electrochemical, pharmacological and/or optical systems to transduce signals from the signal generator 12 to recruit neurons in nerve 20."

New Claims 42 to 59 find basis in new Claims 20 to 41.

Finally, new Claims 60 to 77 are method claims which find basis in new Claims 20 to 59.

In the outstanding Office Action, Claims 1 and 19 were rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs (US 5,314,495). The above reformulated claims are believed to distinguish the present invention over the cited references for the following reason.

Claim 20 recites:

"A system for alleviating phantom limb pain and selectively delivering stimulation signals to a patient having a limb stump, comprising:

a prosthetic limb that is attachable to the patient's limb stump, the prosthetic limb including a plurality of sensors that produce sensory signals;

a signal generator for producing electrical stimulation signals to stimulate one or more selected sensory nerve fibers of a severed limb nerve, the electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated;

a microprocessor that receives the sensory signals and is programmed to cause the signal generator to produce the electrical stimulation signals and to deliver the electrical stimulation signals to the one or more selected sensory nerve fibers in order to provide sensations to the patient that appear to arrive from the prosthetic limb, wherein the selection of the one or more sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors;

means for transmitting the sensory signals from the plurality of sensors to the microprocessor; and

means for transmitting the electrical stimulation signals to the selected sensory nerve fibers;

wherein the means for transmitting the electrical stimulation signals to the selected sensory nerve fibers includes a plurality of electrodes adapted for implantation in close proximity to the severed limb nerve and wherein each electrode is in close proximity to different sensory nerve fibers of the severed limb nerve." [Emphasis added]

Kovacs teaches that "As shown in FIG. 9, for stimulation purposes, each pair of microelectrodes 22, 24 is controlled by a stimulus latch (or flip flop) 282. Signals from a control processor (not shown) updates the value in the latch; if the value is of one value, for example 1, latch 282 will cause switch 284 to close. Current from source 32 will then pass between microelectrodes 22, 24 as before for stimulation purposes." (column 12, lines 41-48) and that "...the pairs of microelectrodes need not be selected or addressed on a row by row basis but can be in any arbitrarily selected pattern." (column 12, lines 59-62). It may be seen by the teachings of Kovacs along with accompanying Fig. 9, that the control processor controls the stimulus latches causing the opening or closing of switch thus causing a current from a current source to pass between the microelectrodes. The control processor is simply used to select through which microelectrode pair the current will flow, it does not modulate the current to generate stimulation signals, it simply allows a straight current to flow to the nerve. Furthermore, the arbitrarily selected pattern thought by Kovacs refers to a pattern of activation of the various microelectrode pairs, it does not refer to an <u>electrical stimulation signal pattern</u> delivered to <u>one or more selected sensory nerve fibers</u>. This teaches away from a signal generator for producing <u>electrical stimulation signals to stimulate one or more selected sensory nerve fibers of a severed limb nerve, the electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated</u> and a microprocessor that receives the sensory signals and is programmed to cause the signal generator to produce the

electrical stimulation signals and to deliver the electrical stimulation signals to the one or more selected sensory nerve fibers.

Furthermore, Kovacs does not teach that the selection of the one or more sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors.

The Applicant therefore submits that Claim 20 is not anticipated by Kovacs Furthermore, the Applicant submits that Claims 21-41 directly or indirectly dependent on allowable Claim 20 are also not anticipated by Kovacs for at least the same reason.

The Applicant also submits that Claims 60-69 which are method claims corresponding to allowable Claims 20-41 are also not anticipated by Kovacs for at least the same reason.

Claim 42 recites:

"A system for alleviating phantom limb pain of a patient having a limb stump, comprising:

a signal generator for producing electrical stimulation signals to stimulate one or more selected sensory nerve fibers of a severed limb nerve, the electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated;

a microprocessor that is programmed to cause the signal generator to produce the electrical stimulation signals and to deliver the electrical stimulation signals to one or more selected sensory nerve fibers in order to alleviate phantom limb pain, wherein the selection of the electrical stimulation signals is based on feedback from the patient; and

means for transmitting the electrical stimulation signals to the selected sensory nerve fibers;

wherein the means for transmitting the electrical stimulation signals to the selected sensory nerve fibers includes a plurality of electrodes adapted for implantation in close proximity to the severed limb nerve and wherein each electrode is in close proximity to different sensory nerve fibers of the severed limb nerve." [Emphasis added]

For the same reasons as for Claim 20, the Applicant submits that Kovacs teaches away from a signal generator for producing electrical stimulation signals to stimulate one or more selected sensory nerve fibers of a severed limb nerve, the electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated and transmitting the electrical stimulation signals to the selected sensory nerve fibers.

Furthermore, Kovacs does not teach that the selection of the electrical stimulation signals is based on feedback from the patient.

The Applicant therefore submits that Claim 42 is not anticipated by Kovacs Furthermore, the Applicant submits that Claims 43-59 directly or indirectly dependent on allowable Claim 42 are also not anticipated by Kovacs for at least the same reason.

The Applicant also submits that Claims 70-77 which are method claims corresponding to allowable Claims 42-59 are also not anticipated by Kovacs for at least the same reason.

Claims as originally filed were rejected 1, 11 and 19 under 35 U.S.C. 102(b) as being anticipated by Schulman (US 4,232,679). The above reformulated claims are believed to distinguish the present invention over the cited references for the following reason.

Schulman teaches of a stimulator to"...provide stimulating pulses. These pulses by means of electrode leads 15a and 15b are assumed to be applied to electrode pair A, located at tissue A (not shown), e.g., a nerve or a muscle to be stimulated." (column 4, lines 40-43). Schulman

teaches the use of stimulating pulses applied to a nerve or muscle but does not teach electrical stimulation signals to stimulate one or more selected sensory **nerve fibers** of a severed limb nerve, the electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated. Furthermore, Schulman does not teach a prosthetic limb that is attachable to the patient's limb stump, the prosthetic limb including a plurality of sensors that produce sensory signals with a microprocessor that receives the sensory signals and is programmed to cause the signal generator to produce the electrical stimulation signals and to deliver the electrical stimulation signals to the one or more selected sensory nerve fibers where the selection of the one or more sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors.

The Applicant therefore submits that Claim 20 is not anticipated by Schulman Furthermore, the Applicant submits that Claims 21-41 directly or indirectly dependent on allowable Claim 20 are also not anticipated by Schulman for at least the same reason.

The Applicant also submits that Claims 60-69 which are method claims corresponding to allowable Claims 20-41 are also not anticipated by Schlman for at least the same reason.

As mentioned above, Schulman teaches the use of stimulating pulses applied to a nerve or muscle but does not teach electrical stimulation signals to stimulate one or more selected sensory **nerve fibers** of a severed limb nerve, the electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated. Furthermore, Schulman does not teach that the selection of the electrical stimulation signals is based on feedback from the patient.

The Applicant therefore submits that Claim 42 is not anticipated by Schulman Furthermore, the Applicant submits that Claims 43-59 directly or indirectly dependent on allowable Claim 42 are also not anticipated by Schulman for at least the same reason.

The Applicant also submits that Claims 70-77 which are method claims corresponding to allowable Claims 42-59 are also not anticipated by Schulman for at least the same reason.

Claims 1-3, and 19 were further rejected under 35 U.S.C. 102(e) as being anticipated by Chen (US 5,824,027). The above reformulated claims are believed to distinguish the present invention over the cited references for the following reason.

Chen teaches of "A nerve cuff adapted for nerve stimulation applications could comprise, for example, two electrodes 34 in each chamber 30 separated longitudinally inside the chamber. A large variety of numbers and arrangements of electrodes 34 could be used for nerve stimulation." (column 8, lines 17-21). Chen teaches of a nerve cuff for nerve stimulation applications but does not teach of electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated. Furthermore, Chen does not teach a prosthetic limb that is attachable to the patient's limb stump, the prosthetic limb including a plurality of sensors that produce sensory signals with a microprocessor that receives the sensory signals and is programmed to cause the signal generator to produce the electrical stimulation signals and to deliver the electrical stimulation signals to the one or more selected sensory nerve fibers where the selection of the one or more sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors.

The Applicant therefore submits that Claim 20 is not anticipated by Chen Furthermore, the Applicant submits that Claims 21-41 directly or indirectly dependent on allowable Claim 20 are also not anticipated by Chen for at least the same reason.

The Applicant also submits that Claims 60-69 which are method claims corresponding to allowable Claims 20-41 are also not anticipated by Chen for at least the same reason.

As mentioned above, Chen teaches of a nerve cuff for nerve stimulation applications but does not teach a of signal generator for producing electrical stimulation signals to stimulate one or more selected sensory nerve fibers of a severed limb nerve, electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated. Furthermore, Chen does not teach a microprocessor that is programmed to cause the signal generator to produce the electrical stimulation signals and to deliver the electrical stimulation signals to one or more selected sensory nerve fibers in order to alleviate phantom limb pain, wherein the selection of the electrical stimulation signals is based on feedback from the patient

The Applicant therefore submits that Claim 42 is not anticipated by Chen Furthermore, the Applicant submits that Claims 43-59 directly or indirectly dependent on allowable Claim 42 are also not anticipated by Chen for at least the same reason.

The Applicant also submits that Claims 70-77 which are method claims corresponding to allowable Claims 42-59 are also not anticipated by Chen for at least the same reason.

Claims 1-10, 12-16, 18-19 stand rejected under 35 U.S.C. 102(a) as being anticipated by Riso ("Strategies for providing upper extremity amputees with tactile and hand position feedback" in Technology and Health Care, Fall 1999). The above reformulated claims are believed to distinguish the present invention over the cited references for the following reason.

Riso teaches "...implementing sensation into artificial arms..." (Abstract) with "electrical stimulation to deliver sensor derived information directly to the peripheral afferent nerves within the residual limb" (Abstract) and that "The quality of the perceived sensation, moreover, remains a foreign feeling resembling a vibration, taping or flutter on the skin (page 402, last paragraph). Thus, Riso teaches of implementing sensation into artificial arms but teaches away from electrical stimulation signals approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated. Furthermore, Riso does not teach a microprocessor that receives the sensory signals and is programmed to cause the signal generator to produce the electrical stimulation signals and to deliver the electrical stimulation signals to the one or more selected sensory nerve fibers where the selection of the one or more sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors.

The Applicant therefore submits that Claim 20 is not anticipated by Riso Furthermore, the Applicant submits that Claims 21-41 directly or indirectly dependent on allowable Claim 20 are also not anticipated by Riso for at least the same reason.

The Applicant also submits that Claims 60-69 which are method claims corresponding to allowable Claims 20-41 are also not anticipated by Riso for at least the same reason.

Riso teaches "...implementing sensation into artificial arms..." (Abstract) with "electrical stimulation to deliver sensor derived information directly to the peripheral afferent nerves within the residual limb" (Abstract) and that "The quality of the perceived sensation, moreover, remains a foreign feeling resembling a vibration, taping or flutter on the skin (page 402, last paragraph). Thus, Riso teaches of implementing sensation into artificial arms but teaches away from electrical stimulation signals approximating a pattern of sensations that would

be received from a normal, innervated limb before it was amputated where the selection of the electrical stimulation signals is based on feedback from the patient. Furthermore, Riso teaches of delivering sensor derived information directly to the peripheral afferent nerves, which teaches away from a signal generator for producing electrical stimulation signals to stimulate one or more selected sensory nerve fibers of a severed limb nerve where there are no sensors involved.

The Applicant therefore submits that Claim 42 is not anticipated by Riso Furthermore, the Applicant submits that Claims 43-59 directly or indirectly dependent on allowable Claim 42 are also not anticipated by Riso for at least the same reason.

The Applicant also submits that Claims 70-77 which are method claims corresponding to allowable Claims 42-59 are also not anticipated by Riso for at least the same reason.

In view of the aforesaid amendments and supporting as well as distinguishing arguments Applicant submits that the newly submitted claims are patentable over the cited prior art of record and each rejection has been fully addressed and overcome appropriate support for these amendments are provided throughout this paper. No new matter has been added.

As the claims are believed to be patentably distinguished over the art of record and no other issues appear to be outstanding favorable reconsideration is respectfully requested as well as early issuance of the Notice of Allowance.

Respectfully Submitted,

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